

COASTAL ORTHOPAEDIC
INSTITUTE
235 Hanover Street
and
1030 President Avenue
Fall River, MA 02720

Telephane - 508-646-9525 Fax - 508-679-7177 Fax - 508-675-0001

David M. Boland, M.D.
David W. Bullis, M.D.
James D. Coleman, M.D.
Brad E. Green, D.O.
Jerald W. Katz, M.D.
James Leffers, M.D.
Kevin N. Mable, M.D.
Richard W. Smith, M.D.
James M. Worthington, M.D.

Susan LaPanne, CPA
Practice Administrator

November 30, 1999

Documentation Management Branch (HFA-305) Food & Drug Administration 5630 Fishers Lane - Room 1061 Rockville, MD 20852

RE: Docket # 97N-484S

To Whom It May Concern,

I am a physician who practices orthopaedic surgery in Fall River, Massachusetts. I have become aware that in the September 30, 1999 issue of the Federal Register that there is a proposal to regulate allografts as medical devices.

Bone grafts are frequently used in orthopaedic surgery to supplement deficient areas of bone and for structural support to treat fractures and instabilities. Any increased regulation of allograft materials that would in some way limit access will severely hinder the care of my patient's.

The alternative to allograft is autograft bone which would mean having to make a separate painful incision and remove bone from the patient's iliac crests. This certainly is not helpful for the patient and tends to increase their morbidity and lengthens hospital stay **as** well.

Allografts have been used for years, This is not a new device and should not be treated as such.

Thank you for your kind consideration in this matter.

Since Pely W

Jerald W. Katz, M.D

JWK: pat

9711-4845

COASTAL ORTHOPAEDIC INSTITUTE, P.C.

235 HANOVER STREET FALL RIVER, MASSACHUSETTS 02720

ADDRESS CORRECTION REQUESTED



Documentation Management Branch
(HFA - 305)

Food + Upug administration
5630 Fishers Kane

Baom 1061

Frankville Miller M